

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF WEST VIRGINIA
AT CHARLESTON**

IN RE ETHICON, INC., PELVIC REPAIR SYSTEM PRODUCTS LIABILITY LITIGATION	Master File No. 2:12-MD-02327 MDL 2327
THIS DOCUMENT RELATES TO: ETHICON WAVE 6 CASES LISTED IN PLAINTIFFS' EXHIBIT A	JOSEPH R. GOODWIN U.S. DISTRICT JUDGE

**DEFENDANTS' MEMORANDUM OF LAW IN OPPOSITION TO
PLAINTIFFS' MOTION TO EXCLUDE OR OTHERWISE LIMIT THE OPINIONS
AND TESTIMONY OF DEFENSE EXPERT LAWRENCE LIND, M.D.**

Defendants Ethicon, Inc. and Johnson & Johnson (collectively, “Ethicon”) respectfully submit this Memorandum in Opposition to Plaintiffs’ Motion to Exclude or Otherwise Limit the Opinions and Testimony of Defense Expert Lawrence Lind, M.D. (“Dr. Lind”). (Pls.’ Motion [ECF No. 4877]; Exs. A-F [ECF Nos. 4877-1, 4877-2, 4877-3, 4877-4, 4877-5, 4877-6, 4877-7]; Memorandum [ECF No. 4878].)

INTRODUCTION

Plaintiffs seek to bar the testimony of Dr. Lind as to Prolift and Gynemesh PS. Ethicon offers Dr. Lind as a general expert on the design, safety, and efficacy of Prolift, Gynemesh PS, TVT, and TVT-Exact. Plaintiffs support their motion by mischaracterizing the scope and basis for Dr. Lind’s opinions – incorrectly suggesting his opinions on the safety and efficacy of Gynemesh PS and Prolift are based solely on his personal experience, and claiming he “cherry picked” his support from scientific literature which are “replete with biases.” Contrary to Plaintiffs’ framing of these opinions, Dr. Lind properly combines his experience as a surgeon

and teacher, and his review of the medical literature – including Level 1 studies – to opine on the safety and efficacy of Prolift and Gynemesh PS. Plaintiffs’ attempt to distort Dr. Lind’s deposition testimony and disregard his distinguished qualifications and experience as well as his extensive review of the scientific literature fails to present a true *Daubert* challenge. Ultimately, Dr. Lind’s opinions would be very instructive to the jury and should be admitted at trial.

DR. LIND’S BASES FOR HIS EXPERT OPINION

Dr. Lind is board-certified in obstetrics, gynecology, and female pelvic medicine and reconstructive surgery. (Pls.’ Ex. C (Lind Report) at 2.) He is a member of the American Urogynecologic Society (AUGS), a fellow of the American College of Obstetrics and Gynecology (ACOG), and a fellow of the American College of Surgeons (ACS). (*Id.*) He completed his residency in obstetrics and gynecology and is fellowship-trained in urogynecology and pelvic reconstructive surgery. (*Id.*) Since 1996, he has been and continues to be the chief of the Division of Urogynecology and Pelvic Reconstructive Surgery at North Shore University Hospital and Long Island Jewish Medical Center (now known as Northwell Health), a tertiary referral hospital. (*Id.*; *see also* Ex. A (Lawrence Lind, M.D. 10/11/17 Dep. Tr. (“Lind Dep.”) 18:10-19:5).) Dr. Lind teaches obstetrics and gynecology at Northwell Health-Hofstra University School of Medicine, and has trained residents and fellows on surgical repairs of pelvic organ prolapse (POP). (Pls.’ Ex. C (Lind Report) at 2.)

Dr. Lind has extensively researched and contributed to the medical literature on the surgical treatment of pelvic floor disorders. He has authored and co-authored numerous articles in peer-reviewed scientific literature and book chapters in the field of urogynecology. (*Id.*) He has presented abstracts and posters at meetings of professional medical societies. (*Id.*) He is also on the review board of the scientific journals *Obstetrics and Gynecology and International*

Urogynecology. (*Id.*) Dr. Lind is currently conducting animal research assessing how polypropylene mesh behaves when implanted in rats. (Ex. A (Lind Dep.) at 32:17-33:7.)

Thus far in his surgical career, Dr. Lind has performed “approximately 100 Prolifts” (Pls.’ Ex. C (Lind Report) at 2) and “hundreds” of surgeries implanting Gynemesh PS, which he continues to perform today. (Ex. A (Lind Dep.) at 185:23-186:4.) If complications arise, Dr. Lind has experience treating and managing those complications. Indeed, other surgeons in the New York metropolitan area have referred mesh complications cases for Prolift and Gynemesh PS to Dr. Lind. (Pls.’ Ex. C (Lind Report) at 2.)

Dr. Lind’s report combines this extensive clinical experience with a reliance upon a large pool of scientific literature and studies as well as the evaluation of many physicians and medical organizations to form opinions to a reasonable degree of medical certainty. (*Id.* at 3.) The materials Dr. Lind cites include long-term data from randomized controlled trials (Level 1 evidence) and the official statements of medical societies. (*See generally* Pls.’ Ex. C (Lind Report).) In addition to the materials directly cited in his report, Dr. Lind also reviewed extensive amounts of medical literature identified on his reliance list. (*See generally* Pls.’ Ex. E (General Reliance List); Pls.’ Ex. F (Supplemental Reliance List).) In short, Dr. Lind’s opinions merge his extensive training and experience as a surgeon and teacher with an exhaustive wide-ranging review of the medical literature.

LEGAL STANDARD

Ethicon incorporates by reference the standard of review of *Daubert* motions as articulated by the Court in *Edwards v. Ethicon, Inc.*, No. 2:12-cv-09972, 2014 WL 3361923, at *1-3 (S.D.W. Va. July 8, 2014).

ARGUMENT

I. Dr. Lind is well qualified to opine about the safety and efficacy of Prolift and Gynemesh PS based on his education, training, clinical practice, and review of the medical literature.

As discussed above, Dr. Lind is a highly trained board certified urogynecologist and surgeon with a subspecialty in female pelvic medicine and reconstructive surgery. (Pls.’ Ex. C (Lind Report) at 2.) Plaintiffs themselves “do not challenge his qualifications as such.” (Pls.’ Mem. in Supp. of Mot. to Exclude Dr. Lind (“Pls.’ Mem.”) at 1.) Contrary to what Plaintiffs suggest, Dr. Lind does not rely solely on his status as a urogynecologist to qualify him to opine on the safety and efficacy of Prolift and Gynemesh PS. (*See id.* at 4.) Rather, Dr. Lind’s opinions rest not only on his own practice but on his historical review of peer-reviewed medical literature, including randomized controlled trials and systematic reviews and meta-analyses, as well as his own experience in teaching medical professionals and the statement of the professionals themselves through their professional associations. (*See* Pls.’ Ex. C (Lind Report) at 3.) In fact, Plaintiffs acknowledge that Dr. Lind has read and relied on various scientific literature to form his opinions. (*See, e.g.*, Ex. A (Lind Dep.) at 48:15-49:1 (Q. And you have read the systemic review that’s been published by Maher, et al. in Cochrane . . . A. I have read it, yes. Q. And you are relying upon it for basis of several of your opinions in this expert report; is that correct? A. Yes.).) Thus, Plaintiffs’ assertion that “he has offered no validation, other than his personal opinion” is disingenuous. (Pls.’ Mem. at 5.)

Plaintiffs challenge the reliability of Dr. Lind’s expert testimony about the safety and efficacy of POP products at issue because he has not, for example, personally published any peer-reviewed articles regarding Gynemesh PS or Prolift, or been asked to consult on the design of a vaginal mesh. (*See* Pls.’ Mem. at 4-5.) Plaintiffs’ critique of his qualifications underscore their misunderstanding of *Daubert* scrutiny. This Court has made clear that a surgeon with Dr.

Lind's experience is allowed to examine the literature – as he has done here – and offer opinions on a product's safety and efficacy. *See, e.g., In re Ethicon, Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2017 WL 988838, at *3 (S.D.W. Va. Mar. 10, 2017) (denying plaintiffs' motion to exclude testimony by board-certified obstetrician-gynecologist regarding the "safety and efficacy" of SUI and POP products); *Tyree v. Boston Scientific Corp.*, 54 F. Supp. 3d 501, 585 (S.D.W. Va. 2014) (permitting board-certified urologist with no stated "design" expertise to testify to the safety and effectiveness of mesh as he had "performed almost 3,000 sling procedures," and "cites numerous studies and academic papers throughout his expert report to support his opinion that the Obtryx is both safe and effective"); *Wilkerson v. Boston Scientific Corp.*, No. 2:13-cv-04505, 2015 WL 2087048, at *24 (S.D.W. Va. May 5, 2015) (rejecting attempt to exclude testimony by an obstetrician-gynecologist on the "safety and effectiveness" of midurethral slings and holding that the clinician's extensive experience implanting the devices "along with his review of the existing literature, provides a reliable basis for his opinions on the safety and efficacy of the Advantage Fit."). Dr. Lind's experience as a surgeon who has implanted "approximately 100 Prolifts" and "hundreds" of Gynemesh PS implants, and as a teacher who has trained residents and fellows on surgical repairs of pelvic organ prolapse coupled with his extensive review of peer-reviewed medical literature, is sufficient to support his opinions that Prolift and Gynemesh PS are safe and effective.

Moreover, as this Court has recognized, *Daubert* does not require independent verification of "every single clinical experience [the physician] had over the course of his career," because otherwise, "the court would never make it past pre-trial motions." *Bellew v. Ethicon, Inc.*, No. 2:13-cv-22473, 2014 WL 12685965, at *19 (S.D.W. Va. Nov. 20, 2014); *see also Winebarger v. Boston Scientific Corp.*, No. 2:13-cv-28892, 2015 WL 1887222, at *34

(S.D.W. Va. Apr. 24, 2015) (finding that expert's lack of "exact statistics" about the outcome of his patients did not render his opinions based on personal experience unreliable and that "such detail is not required under *Daubert* to opine as to the 'large-scale safety and efficacy of the Uphold device'"') (emphasis in original); *Trevino v. Boston Scientific Corp.*, No. 2:13-cv-01617, 2016 WL 2939521, at *33 (S.D.W. Va. May 19, 2016) (same). For the same reasons, the Court should reject Plaintiffs' argument here. Simply because Dr. Lind did not conduct, for purposes of publication, an epidemiological study utilizing either Prolift or Gynemesh PS does not render his experience unhelpful or unscientific. Accordingly, Plaintiffs' request to limit Dr. Lind's testimony on this basis is misplaced.

II. Dr. Lind supports his opinions with a reliable methodology, and that Plaintiffs may disagree with Dr. Lind's conclusion goes to weight, not admissibility, and can be addressed on cross-examination.

Plaintiffs' claim that Dr. Lind's opinion relies on selective results of scientific literature and does not account for contrary studies fails to accurately characterize his deposition testimony. In each instance, Dr. Lind supported his opinions with citations to medical literature and explained why he did not rely on certain contrary studies. *See In re: Ethicon Inc. Pelvic Repair Sys. Prod. Liab. Litig.*, MDL No. 2327, 2016 WL 4493660, at *4 (S.D.W. Va. Aug. 25, 2016).

Plaintiffs, for example, took issue with the 2016 Cochrane Review by Maher, et al., on transvaginal mesh or grafts compared with native tissue repair for prolapse that Dr. Lind relied on and questioned his failure to consider its discussion about bias in an article by Withagen, et al, which compared trocar-guided mesh with conventional vaginal repair in vaginal prolapse. (*See* Pls.' Mem. at 6-12.) Contrary to Plaintiffs' argument, however, Dr. Lind did not ignore the Cochrane Review's findings regarding potential bias in the Withagen article owing to a larger number of patients having had sacrocolpopexy in the vaginal mesh group than in the

conventional group. (*Id.*) Instead, Dr. Lind explained, when considering the issue in the context of “urogynecology and prolapse . . . the fact that they’re exactly matched by their randomization in prolapse stage makes that bias that [Plaintiffs] pointed out *not clinically significant* or scientifically significant for me.” (Ex. A (Lind Dep.) at 83:22-84:5) (emphasis added).

Plaintiffs make much of the fact that Dr. Lind testified that he could not recall how many of the 20 studies listed in Appendix 3 to an article he relied on by Schimpf, et al., involved Prolift or Gynemesh PS. (*See* Pls.’ Mem. at 12-13.) Plaintiffs’ argument is meritless because Dr. Lind’s report includes citations to other studies involving Prolift and Gynemesh PS. Thus, it is irrelevant whether Dr. Lind could recall the specific products involved in studies listed in an appendix to *one* article. He relied on results of the article written by Schimpf, et al., together with the results of numerous other studies. (*See* Pls.’ Ex. E (General Reliance List); Pls.’ Ex. F (Supplemental Reliance List).) *See also* Tyree, 54 F. Supp. 3d at 559-60 (“Dr. Blaivas’s failure to recall which articles supported his opinion as to safety is an insufficient reason to find his methodology unreliable” because he “has extensive experience . . . and considered scientific literature in forming his opinions as evidenced by his relied upon list.”) (internal citations omitted).

Plaintiffs also mischaracterize Dr. Lind’s testimony regarding ACOG’s 2016 Advisory Statement, which reclassified mesh for pelvic organ prolapse from Class 2 to Class 3. (*See* Pls.’ Mem. at 14-15.) Plaintiffs took issue with Dr. Lind’s failure to include that ACOG updated its Committee Opinion from 2011 with a practice advisory in 2016 in his report. (*See id.*) Dr. Lind explained, however, that based on his “20 years of getting [C]ommittee [O]pinions,” that ACOG’s statements are “educational” and when there is more information, “ACOG tends to replace things so that students, residents are not reading older versions” and that it “does not

carry any significance in terms of not being accurate as of 2011.” (Ex. A (Lind Dep.) at 103:20-104:21.) Dr. Lind’s not having included the fact of the update in his report, therefore, does not show any misrepresentation or omission by Dr. Lind.

Finally, Plaintiffs criticize Dr. Lind’s failure to mention in his report an article written by Abbott, et al. (See Pls.’ Mem. at 15-18.) Plaintiffs claim that this article contradicted Dr. Lind’s opinion that a majority of exposures can be treated conservatively. (See *id.*) Yet, Dr. Lind explained in his testimony why he did not cite to the study by Abbott, et al., in that it is “as biased as could be” because it “is a cross-sectional collection of four case series lumped together referred to four of the top people in the nation and does not represent the -- any of the percentages of requiring mesh complete removals as based on the stronger studies, randomized studies” (Ex. A (Lind Dep.) at 113:4-5, 120:2-22.) Dr. Lind’s testimony therefore provided more than “mere blanket accusations of bias for discounting these studies” and “*explained why* he suspected bias.” *Tyree*, 54 F. Supp. 3d at 559 (emphasis in original).

In short, Dr. Lind’s reliance on hundreds of scientific articles is sufficient. Plaintiffs’ attacks on his alleged failure to consider certain contrary studies only go to the weight of Dr. Lind’s testimony, not its admissibility, and should be addressed through cross-examination. *See, e.g., Trevino*, 2016 WL 2939521, at *40 (“If there are certain device-specific publications that [Plaintiffs claim] that Dr. Badylak failed to review in preparing his expert report, the plaintiff is free to ask him about those publications on cross-examination.”); *Huskey v. Ethicon, Inc.*, 29 F. Supp. 3d 691, 735 (S.D.W. Va. 2014) (“Dr. Johnson’s failure to review particular documents goes to the weight of his opinion, not its admissibility.”). Thus, Plaintiffs’ Motion as to this argument is unavailing under *Daubert* and should be denied.

CONCLUSION

For the foregoing reasons, the Court should DENY Plaintiffs' motion to exclude or otherwise limit the opinions and testimony of defense expert Lawrence Lind, M.D., in its entirety.

Respectfully submitted,

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CERTIFICATE OF SERVICE

I hereby certify that on November 6, 2017, I electronically filed the foregoing document with the Clerk of the Court using the CM/ECF system which will send notification of such filing to CM/ECF participants registered to receive service in this MDL.

/s/ Kelly S. Crawford
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